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SUITE 1800

ARLINGTON, VA 22209-3873

EXAMINER

SEVILLA, CHRISTIAN ANTHONY

ART UNIT

PAPER NUMBER

3775

NOTIFICATION DATE

DELIVERY MODE

09/02/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/594,272

Applicant(s)

BRIEST, ARNE

Examiner

CHRISTIAN SEVILLA

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/88)
Paper No(s)/Mail Date 05/10/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 and 19-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Bao et al. (2003/0220649 A1), hereinafter Bao.

Discharge orifice for the material

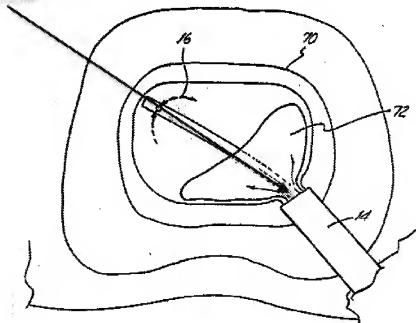


Fig. 5

Regarding claim 1, Bao discloses the claimed invention including an application aid comprising a substantially flexible and tubular or sleeve-shaped outer part which is

composed of at least two components (14, 26) that are coaxially displaceable in one another and a substantially flexible, preferably tubular or sleeve shaped, inner part (18) and a discharge orifice for the material, the discharge orifice for the material being as *shown in annotated Fig. 5 above*, and preferably on the outer part (14).

Regarding claim 2, Bao discloses the claimed invention including gripping means, the gripping means construed as the outer surfaces of elements (14, 26), provided on the components of the outer part (14, 26) for displacing them in one another.

Regarding claim 3, Bao discloses the claimed invention including at least one guide means, construed as the inner surface of element (26; Fig. 2), extending substantially along the entire length of the application aid (10).

Regarding claim 4, Bao discloses the claimed invention including the discharge orifice for the material, as shown in annotated Fig. 5 above, is provided at an end of the outer part (14), and designed in the shape of a tip.

Regarding claim 5, Bao discloses the claimed invention including: in the inside of the outer part (26), at least one membrane-like, construed as a suitable surface coating [0062], is provided capable of being moved at least partially radially outward.

Regarding claim 6, Bao discloses the claimed invention including the at least one membrane-like element, the surface coating [0062], is secured on the inner part (18), as the inner part (18) communicates with the balloon (12) and surface coating to vent gas [0058].

Regarding claim 7, Bao discloses the claimed invention including wherein the at least one membrane-like element, the surface coating discussed supra, is arranged on the outside surface of a balloon-like element, the balloon-like element disclosed by Bao as being a balloon [0062].

Regarding claim 8, Bao discloses the claimed invention including wherein the at least one membrane-like element forms the wall of a balloon-like element, as Bao discloses the coating is on the surface of the balloon [0062].

Regarding claim 9, Bao discloses the claimed invention including wherein the balloon-like element is inflatable, or in other words the balloon is inflatable [0010], and Bao discloses the inner part (18) itself being capable of being subjected to pressure, whether it be air pressure being vented [0058] or due to the fluid pressure of the biomaterial passing through biomaterial conduit (14).

Regarding claim 10, Bao discloses the claimed invention including wherein the balloon-like element, or balloon, is self-expandable, as Bao discloses the balloon is inflatable [0010].

Regarding claim 11, Bao discloses the claimed invention including wherein the at least one membrane-like is secured releasably, as the balloon {on which the membrane-like element is formed} is capable of being detached, via the attachment site (38).

Regarding claim 12, Bao discloses the claimed invention including wherein the least one membrane-like or film-like element is made of a bioabsorbable material, as

the suitable surface coating [0062] is capable of being absorbed into the tissues of the body over time.

Regarding claim 13, Bao discloses the claimed invention including marking means for detecting the discharging of material, as Bao discloses a pressure monitoring component adapted to determine the pressure of biomaterial being delivered [0023].

Regarding claim 14, Bao discloses the claimed invention including wherein the application aid (10) is filled with a material, as the Bao biomaterial {Abstract}, for treatment of bone defects.

Regarding claim 15, Bao discloses the claimed invention including wherein the outer part (14) is filled at least partially with the material, as Bao discloses biomaterial flows through the outer part, or biomaterial conduit (14); the material partially filled in the outer part (14) has a flow adjusted by a valve (28) [0059].

Regarding claim 19, Bao discloses the claimed invention including a kit comprising at least one application aid (10). The kit may include the application aid (10) and a static mixer (106) {Fig. 6}.

Regarding claim 20, Bao discloses the claimed invention including wherein the inner part (18) is tubular or sleeve-shaped, as Bao discloses the inner part has an outer diameter [0059].

Regarding claim 21, Bao discloses the claimed invention including wherein the discharge orifice is provided on the outer part (14), as shown in annotated Fig. 5 supra.

Regarding claim 22, Bao discloses the claimed invention including wherein the gripping means comprise handgrips, and the gripping means is capable gripped with hands.

Regarding claim 23, Bao discloses the claimed invention including wherein the guide means comprises a guide wire, as Bao discloses means for positioning the balloon in the form of a guide wire [0061].

Regarding claim 24, Bao discloses the claimed invention including wherein the balloon-like element is inflatable {paragraph [0010], line 10}, and the inner part (18) itself is capable of being subjected to pressure.

Regarding claim 25, Bao discloses the claimed invention including wherein the balloon-like element is self-expandable, as Bao discloses the preferred balloon provides an optimal combination of extendibility and strength [0072].

Regarding claim 26, Bao discloses the claimed invention including wherein the at least one membrane-like element is made of a bioabsorbable plastic, since the suitable surface coating is a polymeric coating [0062] and the membrane-like element is capable of being absorbed into the body over time.

Regarding claim 27, Bao discloses the claimed invention including wherein the balloon-like element is made of a bioabsorbable material, as Bao discloses preferable balloon materials include polymeric materials [0082] and the balloon-like element is capable of being absorbed into the body over time.

Regarding claim 28, Bao discloses the claimed invention including wherein the balloon-like element is made of a bioabsorbable plastic, as Bao discloses preferable

balloon materials include polymeric materials [0082] and the balloon-like element is capable of being absorbed into the body over time.

Regarding claim 29, Bao discloses the claimed invention including the balloon-like element is made of a shape-memory material, the shape memory material construed as preferable balloon materials that include polymeric materials [0082].

Regarding claim 30, Bao discloses the claimed invention including wherein the balloon-like element is made of a shape-memory material, the shape memory material construed as preferable balloon materials that include polymeric materials [0082].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao in view of Bao et al. (US 5047055), hereinafter Bao '055.

Bao fails to disclose only the volume between the inner part and/or the at least one membrane-like or film-like element and the wall of the outer part is filled with the material; and only the volume to the inside of the at least one membrane-like or film-like element is filled with the material.

Attention however is directed to Bao '055 which teaches an implant in which material is confined only to the region within the surface of the implant only: a hydrogel

intervertebral disc (10) surrounded by a natural annulus fibrosus (16) {col. 7, lines 25-33}

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Bao in view of Bao '055 to construct the device wherein only the volume between the inner part and/or the at least one membrane-like or film-like element and the wall of the outer part is filled with the material; and only the volume to the inside of the at least one membrane-like or film-like element is filled with the material. Doing so would have confined the material within a well-defined region, thus adapting the device for forming prosthetic devices in the body of desired shapes.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bao in view of Chappius (US 6565572).

Bao fails to disclose both the volume between the at least one membrane-like element and the wall of the outer part and also the volume within these elements is filled with the material.

Attention however is directed to Chappius which teaches a medical device wherein bone cement is delivered with a syringe {col. 4, line 12}; and cement is located about an anchor {col. 4, lines 16-19}.

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Bao in view of Chappius to construct the device wherein both the volume between the at least one membrane-like element and the wall of the outer part and also the volume within these elements is filled with the material.

Doing so would have increased the level of fixation between the membrane and surrounding tissue, thereby enhancing the fusion of bone fragments.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bao in view of Stone et al. (US 6387130), hereinafter Stone.

Bao differs from the current invention in that it fails to disclose the guide wire extends inside the inner part (18).

Attention however is directed to Stone which teaches an implant system wherein a plurality of implants are slidably movable over an elongated member (claim 1) and the elongated member comprises a flexible wire (claim 4).

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Bao in view of Stone to construct the guide wire extends inside the inner part. Doing so would have permitted more accurate positioning of the inner part, thereby improving the surgeon's ability to position materials in the body.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN SEVILLA whose telephone number is (571)270-5621. The examiner can normally be reached on Monday through Thursday, 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THOMAS C. BARRETT can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTIAN SEVILLA/
Examiner, Art Unit 3775

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